REMARKS

It is noted that the rejections based on Lederman Patent No. 6,210,318 have been withdrawn and that new rejections have been made based on Dobak Patent No. 5,827,171 (hereinafter Dobak '171) and Dobak Patent No. 5,820,542 (hereinafter Dobak '542).

Claims 17 and 19-20 have been rejected as indefinite under 35 U.S.C. § 112. Applicant agrees that claims 17 and 19 failed to provide an antecedent for the recitation "fluid conducting tube" and claim 17 has, accordingly, been amended to make it dependent upon claim 16 rather than upon claim 2. Similarly, claim 20 has been amended to recite "fluid carrying" rather than "gas carrying" such that claim 26 now provides an antecedent. Thus, it is believed that each of the rejections based on § 112 has been overcome by amendment.

Claims 1-11, 13, 14, 16, 17, 23-26 and 28-30 have been rejected as anticipated by Dobak '171. Claim 1, upon which claims 1-19, 28, and 29 depend, has been amended as has claim 30. The amendment to claim 1 is such that the claim now recites that the balloon is attached to a shell which is adapted to hold it adjacent to the inside surface of a wall of an arterial vessel such that in the deflated condition, substantially the whole of the balloon lies closely adjacent to the wall of the vessel and, in the inflated condition, the balloon projects into said vessel from said wall. The device of Dobak '171 is fundamentally different from that recited in the claim. There is no shell in the device of Dobak '171 which simply discloses an expandable device having an inner and an outer balloon with the outer balloon encapsulating a stent which holds the outer balloon at the desired diameter. The device is then placed in a blood vessel such that the balloons are coaxial with the vessel and control fluid is pumped into and evacuated from the space between the balloons. An axially located port is provided to permit blood to flow into the inner balloon and then be forced out in a direction opposite to the direction in which it entered

the inner balloon when the inner balloon is contracted by the pumping of fluid into the space between the inner and outer balloons. Thus, the device of Dobak '171 provides in-and-out flow blood. In this regard, Applicants note that the Examiner has taken the view that a third balloon, element 18, which is shown in some of the embodiments of Dobak '171 corresponds to the "shell" of the present invention. However, outer balloon 18 is not a shell and has a function completely different from the shell recited in the rejected claims. As disclosed at column 5, lines 14 and 15, Dobak '171 plainly says:

> "In some embodiments, a protective balloon 18 is not required."

Dobak '171 goes on to say, at column 5, lines 16-19 that:

> "The balloons 14, 16, 18 are made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the balloon is increased further."

The shell recited in the claims of the present application is incapable of expansion. To more fully bring out this distinction, claim 1 has also been amended to recite that the shell is non-expandable. As may clearly be seen from Figure 2 of the present application, it is only the balloon or chamber which expands when inflated.

With regard to claims 3, 24 and 29, the stent of Dobak '171 is attached to balloon 16, but not to balloon 14. Plainly, balloon 14 is compressed and expanded without any movement of stent 20 located in and attached to balloon 18. Thus, balloon 14 cannot be said to be attached or to be coupled, as now recited, to stent 20.

Claims 4-9 are patentable for the same reasons as claims 1-3. Dobak '171 does not disclose a stent covered with a fabric as recited in claim 10. The stent of Dobak '171 cannot be covered with a fabric because the stent is buried in balloon 16. In contrast, the stent of the

present invention and of claim 10 can be covered with a fabric because the stent presents an exposed surface which the stent of Dobak '171 is incapable of doing. The same analysis applies to claim 11 because the balloon 16 of Dobak '171 prevents any coating from being applied to his stent.

With regard to claims 13 and 14, it is believed that the claims patentably distinguish from Dobak '171 as previously written, but clarifying amendments have been made to make it even more clear that when the balloon of the present invention extends around the full circumference of the lumen of the stent frame, there is substantially no space between them and that, as recited in claim 14, the balloon or chamber extends around only a portion of the circumference of the stent in the embodiment recited in that claim.

Claims 16 and 17 are patentable for the same reasons as the claims upon which they depend. Claims 23 and 30 are fundamentally different from the teachings of Dobak '171 and the portion of Dobak '171 quoted in the rejection has no relevance to these claims. For the reasons stated above, Dobak '171 completely fails to disclose the shell recited in these claims and does not disclose that the balloon is expanded away from the shell and contracted toward the shell such that when deflated, it is adjacent to the inner wall of the vessel.

With regard to claim 26, the rejection based on Dobak '171 is plainly misplaced. The entire device of Dobak '171 is deployed intraluminally whereas claim 6 recites deploying the fluid pressure source by forming an aperture in the wall of the aorta or other artery and connecting a fluid conducting tube from the fluid pressure source to the balloon or chamber. Dobak '171 does not disclose the formation of such an aperture and, given the construction of the Dobak '171 device, the formation of such an aperture would be severely harmful to the patient because the patient would lose blood through the aperture.

The rejection of claim 28 over Dobak '171 is also plainly misplaced. While this claim was believed to be plainly patentable in its original form, it has been amended to recite that the balloon prevents blood from flowing over the surface of the shell which was plainly intended by the original language. As previously noted, there is no shell disclosed in Dobak '171 and protective balloon 18 is simply another balloon and not a non-expandable shell.

Claims 1-17, 23-26 and 28-30 have been rejected as anticipated by Dobak '542. It is noted that the rejections of claims 1-11, 13, 14, 16, 17, 23-26 and 28-30 are identical to the rejections based on Dobak '171. Thus, the discussion regarding the rejection of these claims based on Dobak '171 is equally pertinent to the rejection of these claims over Dobak '542 because the relevant disclosures of the two Dobak patents are identical.

An additional rejection of claims 12-15 as anticipated by Dobak '542 has also been made in which the Examiner advances the "alternative interpretation" that the shell is housing 16, relying upon Figure 18 of Dobak '542. This rejection is misplaced because, as to claims 12 and 15, the stent is recited as being "bare", i.e., whereas, at column 13, lines 4 and 5, Dobak '542 states that the housing 16 of the embodiment of Figure 18 "can consist essentially of an expandable stent 20 incorporating a membrane to form a substantially tubular fluid container." The bare stent of claims 12 and 15 cannot be a fluid container because they comprise a stent with apertures in it which cannot function as a container. Rather, the stent of claims 12 and 15 is specifically designed to permit blood flow into a adjacent vessels branching off from a vessel into which the stent is placed. This is the diametric opposite of the structure of Dobak '542.

With regard to claim 13, it is recited that the balloon or chamber extends around the full circumference of the lumen of the frame such that there is substantially no space between them.

Once again, this is the diametric opposite of Figure 18 of Dobak '542 which requires space between balloon 14 and stent 16 in order for blood flow to occur.

With regard to claim 14, the balloon or chamber is recited as not extending around the full circumference of the lumen of the stent, but only a portion thereof. Claim 2, upon which claim 14 is dependent, also recites that the balloon or chamber is coupled to the inner wall of the stent. Balloon 14 of Dobak '542 is not coupled in any way to stent 16.

Lastly, with regard to claims 12-15, Dobak '542 in Figure 18 does not illustrate both a shell and a stent. If, as suggested by the Examiner, the shell is housing 16, there is no stent disclosed with regard to Figure 18 of Dobak. However, Dobak expressly discloses a covered stent and thus does not disclose a shell. Even if the Examiner's erroneous interpretation is accepted, if the stent of Dobak '542 is the shell recited in the claims, Dobak '542 has no stent.

Claims 21, 22 and 27 have been rejected as obvious over both of Dobak '171 and Dobak '542. Given the construction of the Dobak device, it would be impossible to place the stent intraluminally and then connect it to a fluid pressure source placed in the right chest through a sternotomy because the pressure source of Dobak must be intraluminal. In other words, the several balloons of Dobak are inflated by pressure lumens internal to the catheter and it would simply be impossible to connect a pressure source for the balloons of Dobak in an external manner after a sternotomy. Figure 4 of the present application illustrates the manner in which a pressure source is connected to the balloon of the present invention. As shown in this embodiment, tube 18 communicates with space 16 inside of balloon 14 by transversely connecting with shell 12. Such a deployment is so fundamentally different from Dobak that Dobak cannot be considered to suggest it. Similarly, the performance of an aortotomy is completely at odds with the deployment of the device of Dobak for the same reasons as those

expressed with regard to claim 21. Still again, claim 27 recites a sternotomy and is fundamentally different from Dobak for the same reasons as claim 22.

Claims 19 and 20 are rejected as obvious over Dobak '171 or Dobak '542 in view of Lederman. Claims 19-20 are patentable for the reasons expressed with regard to the claims from which they depend. Furthermore, claim 19 recites that the gas carrying tube exits the body percutaneously and claim 20 recites that the fluid carrying tube is connected to a port thoracoscopically. For the reasons stated with regard to claims 21, 22 and 27, the connections recited in claims 19 and 20 could not possibly be made with the device or deployment method of Dobak which are confined to intraluminal deployment of the tube.

With regard to the objection to claim 26, the extra comma after 26 has been deleted.

It is believed that the present application is now in condition for allowance. A favorable action is respectfully solicited.

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

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